UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ABBOTT LABORATORIES, INC., and ABBOTT GMBH & CO. KG,	)	
Plaintiffs,	)	
v.	)	**No. 09 C 7968**
APOTEX INC. and APOTEX CORP.,	)	**Judge Rebecca R. Pallmeyer**
Defendants.	)	

MEMORANDUM OPINION AND ORDER

Plaintiffs Abbott Laboratories, Inc. and Abbott GMBH & Co. KG (collectively "Abbott"), are the owners of U.S. Patent Number 5,436,272 (the "'272 Patent"), a medical treatment for obesity using sibutramine hydrochloride, which is marketed under the name Meridia®. Defendants Apotex Inc. and Apotex Corp. (collectively "Apotex") seek to market a generic version. Accordingly, Apotex sought approval from the Food and Drug Administration ("FDA"), certifying that Abbott's patent was both invalid and would not be infringed by the generic version. Such a certification is referred to as a "paragraph IV certification," a reference to the statutory provision that requires it. As required by law, Apotex notified Abbott about the certification by sending a "paragraph IV letter," setting forth Apotex's contentions of invalidity and non-infringement. After receiving Apotex's letter, Abbott filed this infringement suit, triggering a statutory bar that delays any FDA approval of Apotex's application for thirty months from the date the letter was received. Apotex answered the complaint with two affirmative defenses and two counterclaims. Abbott argues that because some of the arguments supporting those affirmative defenses and counterclaims were not included in the paragraph IV letter, Apotex must file a new letter, thereby restarting the thirty-month bar. In the alternative, Abbott asks the court to strike the counterclaims and affirmative defenses that rely on arguments not raised in the letter. For the reasons that follow, Abbott's motion is denied.

BACKGROUND

The statute at issue in this case is referred to as the Hatch-Waxman Act. In it, "Congress struck a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market." *Andrx Pharmaceuticals, Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002). The first interest is served by giving a five-year period of exclusivity to the first company to bring a drug to market, even if it is unpatented. 21 U.S.C. § 355(c)(3)(E)(ii); *Xechem, Inc. v. Bristol-Myers Squibb Co.*, 372 F.3d 899, 900 (7th Cir. 2004). Once that period of exclusivity runs, though, the second interest kicks in, and a generic manufacturer can take advantage of a streamlined process for applying to market a generic copy of the drug. That process allows the generic manufacturer to file an abbreviated new drug application ("ANDA") that relies on the safety and efficacy studies that were the basis for approval of the pioneering manufacturer's original new drug application ("NDA"). 21 U.S.C. § 355(j)(2)(A); *Andrx*, 276 F.3d at 1371. The ANDA must also address the patents that the pioneering manufacturer has identified as claiming the drug; for each such patent, the generic manufacturer must provide certification "(I) that such patent information has not been filed, (II) that such patent has expired, (III) of the date on which such patent will expire, or (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." 21 U.S.C. § 355(j)(2)(A)(vii). These certifications are referred to as paragraph I, II, III, and IV certifications. *Andrx*, 276 F.3d at 1371.

When an applicant's ANDA includes a paragraph IV certification, the applicant must give notice to the patentee and the NDA holder. 21 U.S.C. § 355(j)(2)(B). That notice, referred to as a "paragraph IV letter," must inform the recipients that an ANDA has been filed, and it must include "a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." *Id.* § 355(j)(2)(B)(iv)(II). To save generic manufacturers the cost of bringing a possibly infringing drug to market and to allow pioneering manufacturers to efficiently

challenge an ANDA, the Hatch-Waxman Act treats the filing of an ANDA as an act of infringement. 35 U.S.C. § 271(e)(2)(A); *Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990) (describing § 271(e)(2) as achieving "the creation of a highly artificial act of infringement"). The patentee has 45 days from the receipt of the paragraph IV letter to file an infringement suit. 21 U.S.C. § 355(j)(5)(B)(iii). If no suit is filed, the FDA may approve the ANDA, but if suit is filed, the ANDA may not be approved until the earliest of the following: the date a court determines invalidity or noninfringement, the date the patent expires, or thirty months from the date the patent holder receives the paragraph IV letter. *Id.*

The patent at issue here, the '272 Patent, was granted on July 25, 1995. It will expire on July 25, 2012. Apotex submitted an ANDA to make and sell a generic version of Meridia®, and sent a paragraph IV letter to Abbott dated November 9, 2009. The paragraph IV letter explained why Apotex believed that Claims 1 through 8 of the '272 Patent were invalid on obviousness grounds and why it believed that Claim 4 was not infringed.

Abbott initiated this infringement suit on December 23, 2009, and Apotex answered on January 8, 2010. In its answer, Apotex asserted the affirmative defenses of invalidity and noninfringement. Apotex also included two counterclaims that repeated the allegations of the affirmative defenses and sought declaratory judgments of invalidity and noninfringement. Apotex's answer states that its claims and defenses of invalidity rely on 35 U.S.C. §§ 101 (utility), 102 (novelty), 103 (non-obviousness), and/or 112 (valid specification). Apotex's claim and defense of noninfringement extend to all of the claims of the '272 Patent. With respect to both noninfringement and invalidity, then, Apotex's answer includes theories not raised in the paragraph IV letter.

ANALYSIS

Abbott's motion argues that because Apotex's answer contains theories of invalidity and noninfringement that were not included in the paragraph IV letter, a new letter must be filed or those new theories must be stricken. Abbott argues further that if a new letter is filed, the thirty-month

stay of 21 U.S.C. § 355(j)(5)(B)(iii) must be restarted, presumably at the date on which Apotex filed its answer, which included the new theories. (Abbott's Br., at 2.) The stay began running only in November 2009 and Apotex filed its answer in January 2010, but when a drug generates millions of dollars in sales, every day of exclusivity is significant.

Abbott's first argument is that Apotex's paragraph IV letter does not meet the statutory requirement of including "a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." 21 U.S.C. § 355(j)(2)(B)(iv)(II). Even assuming that by failing to include in its letter every theory that it now asserts in this litigation, Apotex failed to meet the statutory requirement, the issue is not reviewable by this court. The Federal Circuit has squarely held that parties may not "seek a judicial determination of whether a private party's paragraph IV certification complies with 21 U.S.C. § 355(j)(2)(B)." *Minnesota Mining & Mfg. Co. v. Barr Labs, Inc.*, 289 F.3d 775, 783 (Fed. Cir. 2002). Abbott argues to the contrary, attempting to rely on a brief unpublished order, *Abbott Labs v. Alra Labs, Inc.*, No. 92-cv-5806 (N.D. Ill. Dec. 23, 1992), that predates *Minnesota Mining* by ten years, but that attempt must fail. (Abbott's Br., at 6; Abbott's Reply Br., at 3.) So too must Abbott's attempt to argue against *Minnesota Mining*'s holding, which binds this court. (Abbott's Br., at 7-8; Abbott's Reply Br., at 4-5.) Finally, Abbott attempts to argue around *Minnesota Mining*, pointing to the trial court's power, under 21 U.S.C. § 355(j)(5)(B)(iii), to shorten or extend the thirty-month stay when a "party to the action failed to reasonably cooperate in expediting the action." (Abbott's Br., at 8-9; Abbott's Reply Br., at 5.) That power, however, does not extend beyond conduct in the litigation before the court, so it does not cover conduct before the FDA, such as the paragraph IV certification. *Eli Lilly & Co. v. Teva Pharmaceuticals USA, Inc.,* 557 F.3d 1346, 1351 (Fed. Cir. 2009) (*citing Andrx*, 276 F.3d at 1376). The court acknowledges that the theories put forth in this litigation *do* constitute conduct before the court, but extending the stay on that ground would seem to be an end-run around the holdings just discussed. In any event, even if the court could extend the stay based on a difference

between theories in a paragraph IV letter and theories relied on in court, this is not a case where the difference is anything but routine; Apotex has not failed to "reasonably cooperate in expediting the action." 21 U.S.C. § 355(j)(5)(B)(iii).

In the alternative, Abbott asks that the defense theories raised in Apotex's answer but not in its paragraph IV letter be stricken. (Abbott's Br., at 12.) Abbott cites no precedent for such relief. (*Id*.) And, as Apotex explains, there is significant precedent for the contrary view: that parties are not limited to the theories raised in their paragraph IV letters. (Apotex's Br., at 3-5.) Most significantly, the Federal Circuit implicitly endorsed this view in a case in which the district court had awarded attorney fees against parties that submitted baseless paragraph IV letters and engaged in litigation misconduct. *Takeda Chemical Industries, Ltd. v. Mylan Labs, Inc.*, 549 F.3d 1381 (Fed. Cir. 2008). In challenging the award, appellants and amicus argued that affirmance would discourage ANDA filings, but the court rejected that concern, suggesting that such chilling would occur only if the district court had "limit[ed] the filers to the theories raised in their certification letters"–which it had not done. *Id.* at 1390. District courts have gone further than this observation and explicitly held that ANDA filers are not limited to the theories raised in their paragraph IV letters. *Takeda Chemical Industries, Ltd. v. Mylan Labs, Inc.*, No. 03 Civ. 8253, 2005 WL 1457696, at *1 (S.D.N.Y. June 15, 2005); *Aktiebolag v. Kremers Urban Development Co.,* No. 99 Civ. 8928, 2000 WL 257125, at *1 (S.D.N.Y. Mar. 28, 2000); *Smithkline Beecham Corp. v. Apotex Corp.*, No. 98 C 3952, 2000 WL 116082, at *8 (N.D. Ill. Jan. 24, 2000). Abbott presents no compelling policy reasons or other arguments that support differing from this precedent. Thus, the court holds that Apotex is not limited to the invalidity and noninfringement theories raised in its paragraph IV letter.

CONCLUSION

For the foregoing reasons, Abbott's Motion to Require Defendants to Re-File Their Paragraph IV Letter, or in the Alternative, to Strike Certain Affirmative Defenses and to Dismiss Certain Counterclaims [24] is denied.

ENTER:

Dated: July 9, 2010

REBECCA R. PALLMEYER
United States District Judge